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9 APR 2001

510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Applicant

PCK ELECTRONIC INDUSTRY AND TRADE CO, LTD
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CONTACT PERSON: CENGİZ KABAKCI
ASSISTANT GENERAL MANAGER

2. Device Identification

Proprietary Device Name:	Stonolith V5
Common/Generic Device Name:	Extracorporeal Shock Wave Lithotripter
Classification Name:	Lithotriptor, Extracorporeal Shock-Wave, Urological
Product Code:	78 LNS
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.5990

3. Substantial Equivalence

The Stonelith V5 Extracorporeal Shock Wave Lithotripter is substantially equivalent to the following currently marketed devices:

- Medispec Econolith Lithotripter (PMA# P950043)
- Medirex Tripter-X1 Lithotripter (PMA# P920034)

4. Description of Device

Stonelith V5 is a transportable electrohydraulic shock wave lithotripter. The equipment consists of shock wave generator, patient table, operator interface and x-ray fluoroscopic localization unit. Since all of the parts are collected on the body of the unit, it is a complete solution for the lithotripsy needs.

The shock wave generator has an underwater electrode assembly, a high voltage power supply, a closed circuit water supply system with a tank, an ellipsoidal reflector for focusing and a water cushion (rubber membrane) for the acoustic conductivity of the shock waves to the patient. The shock waves generated by the high voltage discharge at the first focal point of ellipsoidal reflector are focused on the second focal point of ellipsoid. The stones to be fragmented are positioned at this second focal point by moving the motorized patient table in 3 axis. The localization is performed with built in u-arm fluoroscopic x-ray unit. The u-arm is preset at the factory to locate the second focal point of the ellipsoid constantly. Before starting the treatment, the stone to be fragmented is placed to the target point and this is checked by taking fluoroscopy at normal and transversal positions of u-arm.

5. Intended Use

The Stonelith V5 Lithotripter is intended to fragment urinary tract stones in the kidney (renal pelvis and renal calyces) and upper ureter.

6. Technological Characteristics

The shock wave characteristics are reported below in Table-1 by taking the described in the consensus standard IEC 61846 "Ultrasonics - Pressure pulse lithotripters - Characteristics of fields" (1998) into consideration. PVDF film type hydrophones are used in the measurements. The details of the measurements/calculations are given in relevant part of 510(k) application. The results are found similar to the predicate device characteristics.

Parameter	Min 14 kV	Typical 20 kV	Max 24 kV
Peak-positive acoustic pressure (Mpa)	57	74	81
Peak-negative acoustic pressure (Mpa)	8	9	9
Rise time (ns)	120	140	145
Compressional pulse duration (ns)	410	460	490
Maximum focal width (mm) (x-y plane)	4,2	4,6	4,7
Orthogonal focal width (mm)	3,2	3,9	4,5
Focal extent (mm)	17	23	26
Focal volume (mm ³)	119	216	288
Distance between the focus and target location (mm) (z axis)	2	4	7
Derived focal acoustic pulse energy (mJ)	6,42	17,2	17,9
Derived acoustic pulse energy (mJ) At R=4 mm radius	32,3	46,4	51,3
Derived acoustic pulse energy (mJ) At R= 7 mm radius	45,8	74,2	79,5

Table-1 Shock Wave Characteristics

7. Clinical Investigations

The clinical investigations are performed at 2 sites with 10 days follow-up to support this application. A total of 64 patients with 73 stones were treated. 39 patients were males and 25 patients were females. The stones sizes treated were between 5 mm and 32 mm. Only one of patients received general anesthesia. The overall success rate of the investigations is measured as 68.7%.

8. Summary of Studies

The Stonolith V5 is designed in accordance with the product safety and performance requirements established in the following standards given in Table-2:

IEC 60601-2-36	Particular Requirements for safety of equipment for extracorporeally induced lithotripsy
IEC 61846	Ultrasonics- Pressure pulse lithotripters - Characteristics of fields (1998)
IEC 60601-1-1	Medical Electrical Equipment-Part 1 General Requirements for Safety” with Ammend 1 and 2
IEC 60601-1-2	Medical Electrical Equipment-Part 1 General Requirements for Safety-2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests
IEC 60601-1-3	Medical Electrical Equipment-Part 1 General Requirements for Safety-3. Collateral Standard: General Requirements for radiation protection in diagnostic x-ray equipment
IEC 60601-2-7	Medical Electrical Equipment-Part 2 Particular Requirements for the Safety of high-voltage generators of diagnostic x-ray generators
IEC 60601-2-32	Medical Electrical Equipment-Part 2 Particular Requirements for the Safety of associated equipment of x-ray equipment

Table-2 Stonelith V5 safety and performance standards

9. Conclusion

The Stonelith V5 is substantially equivalent to the predicate devices. The Stonelith V5 meets the FDA requirements stated in “Guidance for the Content of Premarket Notifications 510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi “issued on Aug 9,2000.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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FEB 11 2002

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Re: K011106
Trade/Device Name: Stonelith V5
Regulation Number: 21 CFR 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: November 13, 2001
Received: November 13, 2001

Dear Mr. Kabakci:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

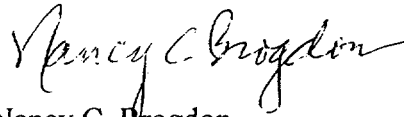
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Applicant: PCK ELECTRONIC INDUSTRY AND TRADE CO, LTD

TURAN GUNES BUL KONRAD ADENAUER CAD
59/1 SANCAK, CANKAYA
06550, ANKARA
TURKIYE

510(k) NUMBER: K011106

DEVICE NAME: STONELITH V5 LITHOTRIPTER

INDICATIONS FOR USE:

The Stonelith V5 Lithotripter is intended to fragment urinary tract stones in the kidney (renal pelvis and renal calyces) and upper ureter.

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011106